U.S. Pharmacopeia
*The Standard of Quality*℠

September 9, 1999

Dockets Management Branch, HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 99N-0193
Supplements and Other Changes to an Approved Application

Dear Sir or Madam:

This letter provides additional comments of the United States Pharmacopeia (USP) to the proposed regulation "Supplements and Other Changes to an Approved Application."[1] USP incorporates by reference its comments submitted in a July 28, 1999 letter to the proposed regulations that were filed with both the Office of Management and Budget and the Dockets Management Branch.

We believe that the proposed regulations are contrary to the legislative intent of the Food and Drug Administration Modernization Act of 1997 (FDAMA). According to the Senate Report for this law, FDA's mission statement includes, among other goals, "promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a manner which does not unduly impede innovation or product availability."[2]

USP therefore recommends that the proposed regulations be amended to reflect the spirit of FDAMA. This can be done by permitting companies that make changes in specifications or in labeling to comply with an official compendium to submit the information in an annual report. By doing so, submissions to the agency will be streamlined, the agency will not be impeding improved product availability, and there will be no adverse effect on the quality of drug products in the marketplace. Attached are USP's recommended changes to the proposed regulations.

If you have any further questions, please do not hesitate to telephone me to arrange a meeting.

Sincerely,

Joseph G. Valentino
Senior Vice President and General Counsel

Attachment

cc: Jerome A. Halperin
Yana R. Mille

[1] 64 Fed. Reg. 34608 (June 28, 1999).
[2] S. Rep. No. 105-43, at 2-3 (1997).

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99N-0193

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## ATTACHMENT

### Recommended Changes to Proposed Regulations

21 C.F.R. § 314.70 Supplements and other changes to an approved application.

(a) Changes to an approved application. (1) The applicant shall notify FDA about each change in each condition established in an approved application beyond the variations already provided for in the application. The notice is required to describe the change fully. Depending on the type of change, the applicant shall notify FDA about it in a supplement under paragraph (b) or (c) of this section or by inclusion of the information in the annual report to the application under paragraph (d) of this section. **An applicant may notify FDA in the annual report of any change made to a specification or in labeling to comply with an official compendium.**

* * *

(d)* * *

(2) These changes include, but are not limited to:

(i) Any change made **to a specification or in labeling** to comply with an official compendium. ~~that is consistent with FDA requirements and provides increased assurance that the drug will have the characteristics of identity, strength, quality, purity, or potency that it purports or is represented to possess;~~

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21 C.F.R. § 601.12 Changes to an approved application.

(d) * * *

(2) * * *

(i) Any change made **to a specification or in labeling** to comply with an official compendium. ~~that is consistent with FDA requirements and provides increased assurance that the drug will have the characteristics of identity, strength, quality, purity, or potency that it purports or is represented to possess;~~